PATENT
Customer No. 22,852
Attorney Docket No. 3495.0008-09

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| In re Application of: | ) | **Appeal No. 2005-0256** |
| | ) | |
| Marc ALIZON et al. | ) | Group Art Unit: 1648 |
| | ) | |
| Application No.: 08/466,921 | ) | Examiner: J. PARKIN |
| | ) | |
| Filed: June 6, 1995 | ) | |
| | ) | |

For: METHOD OF PRODUCING ANTIBODIES TO ANTIGENS OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV 1)



Director
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Sir:

**TRANSMITTAL LETTER**

Applicants in the above-identified application herewith enclose the following:

1. An original **PETITION FOR REVIEW** in an appeal to the United States Court of Appeals for the Federal Circuit of the U.S. Patent and Trademark Board of Patent Appeals and Interferences' **Decision on Appeal** in Appeal No. 2005-0256 mailed on September 26, 2005.

2. A copy of the Decision on Appeal mailed September 26, 2005.

3. A copy of the Board's **Decision on Request for Rehearing** mailed February 28, 2006.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: April 28, 2006

By: _____

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**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

In Re: MARC ALIZON,
FRANCOISE BARRE SINOUSSI,
PIERRE SONIGO,
PIERRE TIOLLAIS,
JEAN-CLAUDE CHERMANN,
LUC MONTGNIER, and
SIMON WAIN-HOBSON, Appellants,

**PETITION FOR REVIEW**

Marc Alizon, Francoise Barre Sinoussi, Pierre Sonigo, Pierre Tiollais, Jean-Claude Chermann, Luc Montagnier, and Simon Wain-Hobson hereby appeal the court for review of the Decision on Appeal entered on September 26, 2005, in Appeal No. 2005-0256 in U.S. Application No. 08/466,921 of the United States Patent and Trademark Office before the Board of Patent Appeals and Interferences. A copy of the Decision is enclosed, together with a copy of the Decision on Request for Rehearing entered on February 28, 2006.

Respectfully submitted,

Dated: April 28, 2006

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# UNITED STATES PATENT AND TRADEMARK OFFICE

## BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MARC ALIZON,
FRANCOIS BARRE SINOUSSI, PIERRE SONIGO,
PIERRE TIOLLAIS, JEAN-CLAUDE CHERMANN,
LUC MONTAGNIER, and SIMON WAIN-HOBSON





Appeal No. 2005-0256
Application No. 08/466,921

HEARD: April 19, 2005

Before WILLIAM F. SMITH, MILLS, and GRIMES, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

## DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 62-73. Claims 39-52, 60, and 61 are pending and are free of rejection.[1] Claims 62-73 read as follows:

[1] An order remanding the application to the examiner to consider a number of issues was entered on June 27, 2002. At that time claims 39-52, 60, and 61 were free of rejection. The remand asked the examiner to review the patentability of those claims in light of recent precedent. Remand, pages 4-5. The remand also stated that a Supplemental Examiner's Answer was not authorized under the then-existing provisions of 37 CFR § 1.193(b)(1). Despite that admonition, the examiner entered a Supplemental Examiner's Answer on March 12, 2004. Appellants responded by way of a Supplemental Reply Brief on May 12, 2004.

While the Supplemental Examiner's Answer was not authorized, appellants have responded thereto and have not urged that they were prejudiced by the examiner's action. Given the length of time it took the examiner to respond to the previous remand and the lack of any apparent prejudice to appellants, we have taken the case up for decision having heard oral argument. We note that the examiner confirmed the patentability of claims 39-52, 60, and 61. Supp. Ex. Ans., pages 12-13.

rtg for reconsid & appeal to court Dlg 11-30-05

Dhr 9-28-05

62. A purified DNA fragment of HIV-1 consisting of a restriction fragment, wherein the fragment hybridizes to the genomic DNA of HIV-1 under hybridization conditions of 20% formamide, 8X SSC, at 37°C, with washes in 2X SSC, 0.1%SDS, at 37°C.

63. The fragment of claim 62, wherein the hybridizing genomic HIV-1 DNA is λJ19 DNA.

64. A cloned DNA fragment of HIV-1, wherein said fragment hybridizes to the genomic DNA of HIV-1 under hybridization conditions of 20% formamide, 8X SSC, at 37°C, with washes in 2X SSC, 0.1%SDS, at 37°C.

65. The fragment of claim 64, wherein the hybridizing genomic HIV-1 DNA is λJ19 DNA.

66. An isolated double-stranded DNA fragment of HIV-1, wherein a strand of said fragment hybridizes to the genomic DNA of HIV-1 under hybridization conditions of 20% formamide, 8X SSC, at 37°C, with washes in 2X SSC, 0.1%SDS, at 37°C.

67. The fragment of claim 66, wherein the hybridizing genomic HIV-1 DNA is λJ19 DNA.

68. An amplified copy of a DNA fragment of HIV-1, wherein said fragment hybridizes to the genomic DNA of HIV-1 under hybridization conditions of 20% formamide, 8X SSC, at 37°C, with washes in 2X SSC, 0.1%SDS, at 37°C.

69. The copy of claim 68, wherein the hybridizing genomic HIV-1 DNA is λJ19 DNA.

70. A vector comprising an HIV-1 DNA fragment, wherein said fragment hybridizes to the genomic DNA of HIV-1 under hybridization conditions of 20% formamide, 8X SSC, at 37°C, with washes in 2X SSC, 0.1%SDS, at 37°C.

71. The vector of claim 70, wherein the hybridizing genomic HIV-1 DNA is λJ19 DNA.

72. A host cell transformed with a vector comprising an HIV-1 DNA fragment, wherein said fragment hybridizes to the genomic DNA of HIV-1 under hybridization conditions of 20% formamide, 8X SSC, at 37°C, with washes in 2X SSC, 0.1%SDS, at 37°C.

73. The host cell of claim 72, wherein the hybridizing genomic HIV-1 DNA is λJ19 DNA.

Claims 62-73 stand rejected under 35 U.S.C. § 112, first paragraph (written description). In addition, claims 68 and 69 stand rejected under 35 U.S.C. 112, second paragraph as being indefinite. We affirm the written description rejection and reverse the indefiniteness rejection.

## Background

The present invention is directed to DNA fragments of human immunodeficiency virus type 1 (HIV-1) and vectors and host cells containing certain of the fragments. The technology described in the specification relates to "cloned DNA sequences hybridizable to genomic RNA and DNA of lymphadenopathy-associated virus (LAV), a process for their preparation and their uses." Specification, page 1.[2] Specifically,

> The present invention aims at providing new means which should not only also be useful for the detection of LAV or related viruses (hereafter more generally referred to as 'LAV viruses'), but also have more versatility, particularly in detecting specific parts of the genomic DNA of said viruses whose expression products are not always detectable by immunological methods.

Id., page 2, lines 10-16. Appellants also state:

> More particularly the invention relates to any fragment corresponding to the above ones, having substantially the same sites at substantially same distances from one another, all of those fragments having in common the capability of hybridizing with the LAV retroviral genomes. It is of course understood that fragments which would include some deletions or mutation which would not substantially alter their capability of also hybridizing with the LAV retroviral genomes are to be

[2] At some point in time, LAV was renamed HIV-1. While the specification of this application refers to LAV, the claims on appeal refer to HIV-1. Consistent with the usage of HIV-1 in the claims under review, we shall refer to the virus as HIV-1.

considered as forming obvious equivalents of the DNA fragments more specifically referred to hereabove.

Id., page 5, first full paragraph.

Discussion

A. Written Description.

A review of the original disclosure reveals that the subject matter set forth in the claims on appeal was not explicitly described at the time this application was filed. This does not mean that those claims lack written description. Eiselstein v. Frank, 52 F.3d 1035, 1038, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995) ("[T]he prior application need not describe the claimed subject matter in exactly the same terms as used in the claims . . ."). However, "[t]he applicant must . . . convey to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991) (emphasis in original). Thus, the analysis becomes whether the as filed application conveys to those skilled in the art that appellants were in possession of the DNA fragments set forth in claims 62-73.

Each claim on appeal requires that the claimed DNA fragment "hybridizes to the genomic DNA of HIV-1 under hybridization conditions of 20% formamide, 8X SSC, at 37°C, with washes in 2X SSC, 0.1% SDS, at 37°C." However, these hybridization and washing conditions are described in the original disclosure of this application as those that were used to compare "LAV with a number of human endogenous viral genomes ...

under non stringent conditions...." Specification, page 12, lines 4-6. Nowhere does the original disclosure of this application describe DNA fragments hybridizing under the claimed conditions as part of appellants' invention. Rather, it appears that appellants have cobbled together disparate portions of the original disclosure in an attempt to claim DNA fragments in a manner not described when the application was filed. As stated in Rengo Co. v. Molins Mach. Co., 657 F.2d 535, 551, 211 USPQ 303, 321 (3d Cir. 1981) "[a]dequate description of the invention guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation."

We also note that since the time the original Appeal Brief and Reply Brief were filed in this case, June 21, 2000 and November 9, 2000, respectively, our appellate reviewing court has addressed written description issues involving DNA. As recognized by appellants in the Supplemental Reply Brief of May 12, 2004, the most relevant precedent is Enzo Biochem, Inc. v. Gen-Probe, Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002) (Enzo II). We have considered appellants' arguments in regard to Enzo II vis-à-vis claims 62-73 of this application but do not find those arguments persuasive.

In considering Enzo II, we note that present claims 62-73 are directed to two separate embodiments. First, there are claims that only require a purified DNA fragment of HIV-1 that consists of a restriction fragment that hybridizes to the "genomic DNA of HIV-1" under the specified hybridization and wash conditions. See, e.g., claim 62. Then there are claims directed to a narrower embodiment wherein the hybridizing

genomic HIV-DNA is λJ19 DNA. See, e.g., claim 63. Appellants argue that the recitation in the claims that the required DNA fragment is a "HIV-1" DNA fragment imposes a structural limitation, as do the claim requirements in regard to hybridization and wash conditions and λJ19 DNA. We agree with appellants that the claims do set forth structural requirements for the claimed DNA fragments as argued. However, we do not find that those structural requirements serve to define a genus of DNA fragments that enjoys proper written descriptive support in the original disclosure of this application. This conclusion includes both the broad and narrow embodiments set forth in the claims on appeal.

The "Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 'Written Description' Requirement," 66 Fed. Reg. 1099 (Jan. 5, 2001) ("Guidelines") were discussed in Enzo II. The court noted that the PTO "has determined that [genus claims to nucleic acids based on their hybridization properties] may be adequately described if they hybridize under highly stringent conditions to known sequences because such conditions dictate that all species within the genus will be structurally similar. See [Guidelines], Example 9, at 35-37." Enzo II, 296 at 1327, 63 USPQ2d at 1615. Appellants rely upon this aspect of Enzo II in the Supplemental Reply Brief. See, e.g., pages 6-7. However, in making these arguments, appellants assiduously avoid recognizing that the hybridization conditions discussed by the court and which appear in Example 9 of the Guidelines are "highly stringent" while the hybridization and washing conditions required by each of claims 62-73 are stated by appellants at page 12 of the specification to be "non stringent." Furthermore, the stated hybridization and

washing conditions are in the specification in order to distinguish the DNA fragments of the present invention from other viral genomes, not as part of defining appellants' invention. Thus, neither Enzo II nor the Guidelines provide appellants any support in their quest to receive patent protection for the genus of DNA set forth in any of claims 62-73.

The written description rejection is affirmed.

B. Indefiniteness.

The examiner rejects claims 68 and 69 under 35 U.S.C. § 112, second paragraph, as being indefinite since

> the reference to 'amplified' copies of HIV-1 DNA fragments is vague and indefinite. The disclosure fails to provide an adequate definition of this phrase. This phrase is confusing since the precise nature of the amplification is not clearly set forth. For instance, it is not readily manifest if the claims are directed toward the amplification and plaque purification of a lambda phage clone containing an HIV-1 insert, PCR amplified HIV-1 fragments (which are clearly not supported by the disclosure), or some other form of amplified DNA. Moreover, Appellants have failed to provide any literature at the time of filing providing a suitable definition. Accordingly, the skilled artisan would not be able to ascertain the precise metes and bounds of the claimed invention.

Supplemental Answer, page 4. From this it appears that the examiner is concerned that the phrase "amplified copy" is confusing unless the nature of the amplification is set forth in the claims. However, the examiner has not established by way of evidence that the manner of amplification necessarily affects the structure of the DNA product or that a person skilled in the art would have difficulty understanding what is meant by "amplified."

The issue raised by the examiner appears to be more directed to the written description requirement of the statute instead of claim definiteness since the examiner relies on the fact that appellants have only described in the original disclosure of this application a single type of amplified DNA, yet now present claims directed to amplified DNA fragments without reference to how the amplification took place. Whether appellants are entitled to claim such a broad genus in this case is an issue more properly raised under the written description requirement.

The examiner's indefiniteness rejection is reversed.

The decision of the examiner is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

William F. Smith
Administrative Patent Judge

Demetra Mills
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES

Appeal No. 2005-0256
Application No. 08/466,921

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dem

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

KJM | SJA
03495-0008-09

# UNITED STATES PATENT AND TRADEMARK OFFICE

## BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES



Ex parte MARC ALIZON,
FRANCOISE BARRE SINOUSSI,
PIERRE SONITO,
PIERRE TIOLLAIS,
JEAN-CLAUDE CHERMANN,
LUC MONTAGNIER, and
SIMON WAIN-HOBSON



Appeal No. 2005-0256
Application No. 08/466,921

ON BRIEF

Before MILLS, GRIMES, and GREEN,[1] Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

## REQUEST FOR REHEARING

Appellants request rehearing of the decision entered September 26, 2005. That decision affirmed the rejection of claims 62-73 for lack of adequate written description.

Appellants assert that the previous decision erred in overlooking the broad teachings in the specification. More specifically, Appellants argue that the specification

[1] The merits panel that issued the initial decision in this appeal included Administrative Patent Judge William F. Smith, who has since retired from the USPTO. APJ Green has replaced APJ Smith on this panel. See In re Bose Corp., 772 F.2d 866, 227 USPQ 1 (Fed. Cir. 1985).

discloses "cloned DNA sequences hybridizable to genomic RNA and DNA" of HIV-1. See the Request for Rehearing, page 3 (citing the first sentence of the specification). Appellants then point to other portions of the specification that set out specific hybridization conditions: page 9, where the specification teaches hybridization of a fragment of HIV-1 DNA to other HIV-1 DNAs; page 11, where the specification teaches that HIV-1 DNA does not hybridize to the DNA of a different virus (HTLV-II) under low stringency conditions; and page 12, where the specification teaches that HIV-1 DNA does not hybridize with "a number of human endogenous viral genomes under non[-]stringent conditions."

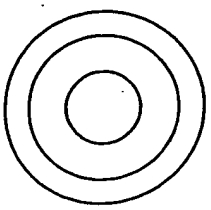
Appellants reason that the hybridization conditions taught on pages 11 and 12 of the specification "were less stringent than the conditions on page 9, and no hybridization of HIV-1 DNA to [other viruses] was detected under these conditions, [so] the skilled artisan would have understood that these were suitable hybridization conditions contemplated by the inventors for use with HIV-1 DNA fragments." Request for Rehearing, page 4. Appellants conclude that "[w]hen these broad teachings of Appellants' specification are taken into consideration, the skilled artisan would have been directed to the claimed hybridization conditions." Id., page 5.

We have considered Appellants' argument but do not find it persuasive. "The purpose of [the written description] provision is to ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification. See . . . Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1561, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991) ('Adequate description of the invention guards against the inventor's overreaching by

insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.' (quoting Rengo Co. v. Molins Mach. Co., 657 F.2d 535, 551, 211 USPQ 303, 321 (3d. Cir. 1981))." Reiffin v. Microsoft Corp., 214 F.3d 1342, 1346, 54 USPQ2d 1915, 1917 (Fed. Cir. 2000).

Here, the claims are directed to fragments of HIV DNA that hybridize to genomic HIV DNA under nonstringent conditions, while the specification only discloses HIV DNA fragments that hybridize under more stringent conditions. Stringency of hybridization conditions is a measure of how similar two DNAs must be in order to hybridize. Under high stringency conditions, only DNAs that are substantially identical will hybridize. See Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 967, 63 USPQ2d 1609, 1615 (Fed. Cir. 2002) (all species within a genus of nucleic acids that hybridize under "highly stringent conditions to known sequences" will be structurally similar).

Under low- or non-stringent conditions, by contrast, DNAs will hybridize to each other despite significant differences in structure. See, e.g., page 11 of the specification (HTLV-I and HTLV-II "hybridize between themselves under reasonably stringent conditions" even though they are different viruses). Thus, the group of DNAs that will hybridize to the genomic DNA of HIV-1 under nonstringent conditions is larger than the group of DNAs that will hybridize under more stringent conditions. The relationship between stringency conditions and the number of DNAs that will hybridize under those conditions can be illustrated as follows, where the inner circle represents the most stringent conditions, and the successively larger circles represent low- and non-stringent conditions:



Each of the circles encompasses the DNAs in the smaller circle(s) within it: each DNA that hybridizes to HIV-1 genomic DNA under highly stringent conditions will also hybridize to it under nonstringent conditions, but the reverse is not true. Thus, the genus of DNAs that will hybridize to HIV-1 genomic DNA under the nonstringent conditions recited in claims 62-73 is larger than the genus of DNAs that will hybridize to the same DNA under the conditions described on page 9 of the specification.

The issue in this case is whether the specification's description shows possession of the larger, claimed genus. See Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991): "[T]he applicant must . . . convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed."

One can show possession of a genus of nucleic acids by describing "a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Besides nucleotide sequence, the species can also be described by reference to deposits or "'disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.'" Enzo, 323 F.3d at 964, 63 USPQ2d at 1613.

Here, Appellants point to the species shown to hybridize under the conditions recited on page 9 of the specification and argue that those species would also be expected to hybridize under less stringent conditions, such as those recited in the claims. The problem with Appellants' argument is that they have pointed to no HIV DNA fragments, described in the specification, that (1) hybridize to HIV genomic DNA under non-stringent conditions and (2) do not hybridize under the stringency conditions set out on the specification's page 9. Appellants have therefore not shown that the specification describes any species encompassed by the claims but not encompassed by the genus of DNAs that hybridize to HIV under the conditions set out on page 9.

That is, all of the species of HIV DNA fragments described in the specification fall into the smallest of the genera discussed above. In terms of the illustration set out above, Appellants are claiming everything encompassed by the largest circle but only pointing to species within the smallest circle for descriptive support. We find that the species relied upon are not representative of the genus claimed. The description provided in the specification does not show possession, at the time of filing, of the genus of HIV DNA fragments defined by claims 62-73.

In summary, we have reconsidered our previous opinion in light of Appellants' request for rehearing but decline to make any changes in the opinion.

REHEARING DENIED

Demetra J. Mills
Administrative Patent Judge )
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)
Eric Grimes ) BOARD OF PATENT
Administrative Patent Judge ) APPEALS AND
)
Lora M. Green ) INTERFERENCES
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